K081371

1/1

SEP 2 4 2008

510(k) Summary

SUBMITTER

Submitted on behalf of:	**Company Name:**	**Leonhard Lang GmbH**
	Address:	Archenweg 56 6020 Innsbruck Austria
	Telephone:	++ 43 / 512 / 33 4 25 7
	Fax:	++ 43 / 512 / 39 22 10
	Registration Number:	8020045
	Owner/0perator Number:	8020045
	by:	**Elaine Duncan**, MS.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082 Telephone: 715-549-6035 Fax: 715-549-5380
Contact Person:	**Elaine Duncan**	
Date prepared:	May 12, 2008	
Trade Name:	Skintact® Pediatric Multifunction Electrodes with DH03 Gel *(and as also to be offered for sale under various private label tradename)*	
Common Name:	Defibrillation Electrodes	
Classification Name:	Dc-defibrillator, low-energy, (including paddles)	
Regulation:	Defibrillators, Automatic, External, 21 CFR § 870.5310	
Regulatory Class	This device is Class III	
Device Panel and Product Code:	74 Cardiovascular, MKJ	
Reason for 510(k) Submission:	new device	

Substantial Equivalence: Skintact® Pediatric Multifunction Electrodes with DH03 Gel are substantially equivalent to the stated predicate devices:

K992977 Hewlett Packard Multifunction Pediatric Defibrillation Electrodes

K072233 Leonhard Lang Skintact® Multifunction Electrodes with DH02 Gel available with different connectors compatible with different devices

Description of device: All Skintact® Multifunction Electrodes are self-adhesive, non-sterile, single use disposable electrodes. The Skintact® Pediatric Multifunction Electrodes with DH03 Gel are composed of the same materials as the predicate device K073322 by Leonhard Lang except the modified DH03 Gel (made by Leonhard Lang).

Indications for use: Skintact® Pediatric Multifunction Electrodes are for use on pediatric patients, less than 8 years of age, or weighing less than 25 kg (55 lbs), for external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and for single use only. These electrodes have been qualified for use with defibrillators delivering a maximum of 100 joules such as: Zoll M and E series and PD1200, 1400, 1600 & 1700 defibrillators; Medtronic LifePak 9, 10, 12 and 20 defibrillators; Philips Heartstart MRx and XL defibrillators; Welch Allyn PIC 30, PIC 40 and PIC 50 defibrillators; Philips Codemaster XE, XL, XL+ and 100 defibrillators.

Basis for Equivalence - performance testing: Biocompatibility testing was conducted and passed ISO 10993 for intact skin. The performance data of Skintact® Pediatric Multifunction Electrodes with DH03 Gel and the predicate device (K072233) met specifications as established in ANSI/AAMI DF80:2003 and IEC/EN 60601-2-4:2003. The introduction of the Skintact® Pediatric Multifunction Electrodes *(and as also to be offered for sale under various private label tradenames)* does not introduce new issues of safety or effectiveness and the Skintact® Pediatric Multifunction Electrodes with DH03 Gel are substantially equivalent to the predicate devices K992977 and K072233.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 2008

Leonhard Lang, GmbH
c/o Ms. Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082

Re: K081371
Trade/Device Name: Skintact® Pediatric Multifunction Electrodes with DH03 Gel
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (Three)
Product Code: MKJ
Dated: September 18, 2008
Received: September 22, 2008

Dear Ms. Duncan:

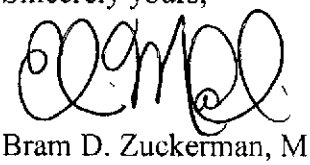
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081371

1/1

Indications for Use

510(k) Number (if known):

Device Name: Skintact® Pediatric Multifunction Electrodes with DH03 Gel

Indications For Use:

Skintact® Pediatric Multifunction Electrodes are for use on pediatric patients, less than 8 years of age, or weighing less than 25 kg (55 lbs), for external defibrillation, pacing, monitoring and cardioversion. The device is non-sterile and for single use only. These electrodes have been qualified for use with defibrillators delivering a maximum of 100 joules such as: Zoll M and E series and PD1200, 1400, 1600 & 1700 defibrillators; Medtronic LifePak 9, 10, 12 and 20 defibrillators; Philips Heartstart MRx and XL defibrillators; Welch Allyn PIC 30, PIC 40 and PIC 50 defibrillators; Philips Codemaster XE, XL, XL+ and 100 defibrillators.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081371